## REMARKS

Claims 18-34 are currently being examined in this application, and stand rejected. Claims 18, 26, and 34 are independent claims, and are amended herein. The applicants respectfully submit that no new matter has been added by this response. It is believed that these amendments and remarks are fully responsive to the Office Action dated **March 5, 2009.**

The Office Action rejects claims 18-34 under 35 U.S.C. § 101 as being directed towards non-statutory subject matter. The position of the Office Action is stated on pages 2-4 of the Office Action, and is not repeated here. Instead, this rejection is summarized in that claims 18-34 stand rejected under the holding of *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (*en banc*); that is, a method/process claim is directed towards patent eligible subject matter only if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." The Office Action further bases the rejection of the device claims and the computer readable medium claim in that these claims fail to produce a tangible result (Office Action, page 4, lines 13-17).

Regarding the claims directed towards a process, claims 26-33, the *Bilski* Court noted that, "the proper inquiry under § 101 is not whether the process claim recites sufficient 'physical steps,' but rather whether the claim meets the machine-or-transformation test." *Id.* at 961 "Thus, it is simply inapposite to the § 101 analysis whether process steps performed by software on a computer are sufficiently 'physical.'" *Id.* at Footnote 25. However claims 26-33 utilize clinical data obtained in a clinical examination. As such, the data corresponds to real world,

tangible things; that is, the data represents properties of actual physical matter (see, e.g., page 6, lines 5, through page 7, line 1, of the Specification). Whereas the *Bilski* Court explained that, "[p]urported transformations or manipulations simply of public or private legal obligations or relationships, business risks, or other such abstractions cannot meet the [statutory subject matter] test because they are not physical objects or substances, and they are not representative of physical objects or substances," 545 F.3d at 963, the present claims transforms data that is representative of physical objects or substances. As such, claims 26-33 are compliant with the statutory subject matter requirements of 35 U.S.C. § 101. Withdrawal of this rejection is respectfully solicited.

Regarding claims 18-25, being directed to a device[1], it is noted that because the *Bilski* holding refers to process claims, not apparatus claims, its holding is inapplicable to claims 18-25. Furthermore, because these claims are directed to a device having a plurality of units to transform data, the applicants assert that these claims at least cover machines under 35 U.S.C. § 101. As such, claims 18-25 are directed towards statutory subject matter. Withdrawal of the rejection of claims 18-25 is now in order and respectfully solicited.

Claim 34 is directed towards a computer readable medium. As such, the claim is not directed to a process, such as in *In re Bilski*, but is instead directed towards a "product" or "thing", and would likely be properly interpreted as being a manufacture under § 101 (*see*, e.g.,

[1] As the Federal Circuit stated in *In re Nuijten*, 500 F.3d 1346, 1355 (Fed. Cir. 2007), under 35 U.S.C. § 101, a machine is a "concrete thing, consisting of parts, or of certain devices and combination of devices." This definition "includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." *Id.* Claims 18-25 surely fall into this statutory category.

MPEP 2106)[2]. Regarding software claims in general, the *Bilski* court "decline[d] to adopt a broad exclusion over software or any other such category of subject matter beyond the exclusion of claims drawn to fundamental principles set forth by the Supreme Court." *In re Bilski*, 545 F.3d at 960. Further regarding claim 34, the Applicants note that "[o]nly when the claimed invention taken as a whole is directed to a mere program listing, i.e., to only its description or expression, is it descriptive material *per se* and hence nonstatutory." MPEP 2106.01. As such, the above holding of *In re Bilski* does not apply to claims that cover computer readable media. In light of these remarks, claim 34 contains statutory eligible subject matter. Withdrawal of the rejection of claim 34 under 35 U.S.C. § 101 is respectfully solicited.

As such, the Applicants hereby assert that the analysis of claims 18-25 and claim 34 presented in the present Office Action fails to comply with the pronouncements of the U.S. Court of Appeals for the Federal Circuit. As such, withdrawal of the rejection of claims 18-25 and 34 under 35 U.S.C. § 101 is now in order and respectfully solicited.

Finally regarding § 101, the Applicants note that "real world" and "tangible result" requirement cited by the Office Action seems to stem from *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998). The *State Street Bank* Court held that the transformation of data in a software-related patent is directed towards patentable

[2] *See also*, Overview of Interim Guidelines for Subject Matter Eligibility, November 22, 2005, ("A 'process' defines actions i.e. inventions that set forth a series of steps or acts to performed. This is often done in the form of method claims. **This is not to be confused with a manufacture** (e.g., memory, **computer-readable medium**) having instructions stored in or on it for causing steps to be performed when the instructions are executed. **Such claims are directed to the manufacture**.") (emphasis added)

subject matter (e.g., in the *State Street Bank* case, which represented "discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price") constitutes:

(a) a "practical application of a mathematical algorithm, formula, or calculation," but

(b) nevertheless, produces "a useful, concrete and tangible result."

In the instant case, the claims provide, among other "useful, concrete and tangible result[s]," by receiving present clinical data ("present data that is clinical data"), as well as previous clinical data, obtained from a subject for a clinical examination (Please also see the definition of "clinical examination" in the Specification beginning on page 6, line 5). Such data is "tangible" because it is, among other things, data obtained from a subject in the course of a clinical examination. Thus, this data is similar to the discrete dollar amounts of *State Street Bank*. Further, because this data is transformed into a determination of validity either by the components of the device claimed in claims 18-25, the steps of the process in claims 26-33 or the computer readable medium of claim 34.

As to the merits of the present Office Action, the following actions have been taken. Claims 18, 19, 22-27, and 30-33 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Toshiba et al. (EP 0389992). The Office Action rejects claims 18-20, 22-28, and 30-33 under 35 U.S.C. § 103(a) as being unpatentable over Toshiba et al. (EP 0389992) in view of Loki et al. (Japan Association of Medical Information, 2002, 13 November, 211-213). The Office Action rejects claims 18-19, 21-27, 29 and 30-33 under 35 U.S.C. § 103(a) as being unpatentable over Toshiba et al. (EP 0389992) in view of Karaoka et al. (Transactions of Information Processing

Society of Japan, 2001, 15 September, 92-99). Lastly, the Office Action rejects claims 18-19, 22-27, and 30-34 under 35 U.S.C. § 103(a) as being unpatentable over Toshiba et al. (EP 0389992).

Because these rejections all primarily rely on Toshiba et al., they will be discussed together below.

Regarding Toshiba et al., its abstract recites:

> "a neural network for learning human judgments of the necessity of re-examination from previously collected sets of medical examination data accompanied with corresponding teacher data indicating whether re-examination was performed for each set of medical examination data".

However, this neural network does not calculate a value indicative of a distance between a position of the medical examination data and a position of the teacher data in the reference patterns. Toshiba et al. does not mention a position of the teacher data in the reference patterns, nor does Toshiba et al. mention a position of a distance in the reference patterns.

To more particularly claim the subject matter regarded as the invention, independent claims 18, 25, and 34 are currently amended to more particularly recite the above distinction between the present application and Toshiba et al.. These amendments find support in the specification on page 13, lines 18-28, and in Fig. 4.

As such, the Applicants assert that, at least, the presently claimed calculating unit of claim 18 and the calculating steps of claims 26 and 34 are patentably distinguishable over the cited art. In light of this distinction, claims 18, 26, and 34 are believed to be patentable and in condition for allowance. Withdrawal of the outstanding rejections of these claims under 35 U.S.C. §§ 102 and 103 is now in order and respectfully solicited.

Further, in light of the believed patentability of claims 18 and 26, it is believed that their dependent claims, claims 19-25 and claims 27-33, respectfully, are also patentable and in condition for allowance. Withdrawal of the outstanding rejections of these claims under 35 U.S.C. §§ 102 and 103 is also now in order and respectfully solicited.

In view of the aforementioned amendments and accompanying remarks, claims 18-34 are in condition for allowance, which action, at an early date, is requested.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicants undersigned attorney at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees that may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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